DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 31, 2014

GENORAY Co., Ltd.
% Ms. Kaitlynn Min
Business Development Manager
GENORAY America, Inc.
3002 Dow Avenue, Suite 420
TUSTIN CA 92780

Re: K141700
Trade/Device Name: PAPAYA Plus, Digital Extraoral Source X-ray System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: October 2, 2014
Received: October 6, 2014

Dear Ms. Min:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141700

Device Name
Digital X-ray Imaging System (Model: PAPAYA Plus)

Indications for Use *(Describe)*
PAPAYA Plus is a digital extraoral source X-ray system intended to produce panoramic and cephalometric(option) images of the oral and craniofacial anatomy for a precise treatment planning in adult and pediatric care. The system is used for dental & skull radiographic examination and diagnosis of teeth, jaw, oral structure, and skull by exposing an X-ray image receptor to ionizing radiation, with a digital imaging capability for taking both panoramic and cephalometric images. And this system can be equipped CUST (Tomographic) option, which is capable of taking cross-sectional radiographic images. These images provide dimensional information for dental implant planning and information about location of impacted teeth.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Exhibit 5 510(k) Summary

Date of Summary Preparation: July 25, 2014

1. Submitter and US Official Correspondent

Submitter:	GENORAY Co., Ltd.
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Official Correspondent (U.S): Kaitlynn Min - Business Manager

Correspondent:	GENORAY America Inc.
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Telephone No.:	714-289-8020
Fax:	714-786-8919
Email:	kaitlynn@genorayamerica.com

2. Establishment Registration Number

3005843418

3. Device Information

Proprietary/Trade Name:	PAPAYA Plus
Common/Usual Name:	Digital X-ray Imaging System
Classification Name:	Extraoral Source x-ray system
Product Code:	MUH
Device Class:	Class II per regulation 21 CFR 872.1800

4. Predicate Device (Equivalent Legally Marketed Device)

PAPAYA Plus (K130419, GENORAY Co., Ltd)
Volumetric Tomography (K063773, Instrumentarium Dental)
Orthopantomograph OP 200 (K046312, Instrumentarium Dental)

5. Description of the Device

PAPAYA Plus is a diagnostic imaging system which consists of multiple image acquisition modes; panorama and cephalometric. And proposed PAPAYA Plus has the CUST imaging option which is used to reconstruct tomographic images from a set of pre-acquired projection radiographic images of the object.

CUST algorithm has already been used for existing panoramic units as the predicate device OP200 (k046312) use the VT (k063773) imaging method. VT imaging method which is similar with CUST is described in the following scientific publication.

CEDERLUND, A.; KALKE, M.; WELANDER, U. Volumetric tomography–a new tomographic technique for panoramic units. Dentomaxillofacial Radiology, 2009, 38: 104-111

6. Indications for use (intended use)

PAPAYA Plus is a digital extraoral source X-ray system intended to produce panoramic and cephalometric(option) images of the oral and craniofacial anatomy for a precise treatment planning in adult and pediatric care. The system is used for dental & skull radiographic examination and diagnosis of teeth, jaw, oral structure, and skull by exposing an X-ray image receptor to ionizing radiation, with a digital imaging capability for taking both panoramic and cephalometric images. And this system can be equipped CUST (Tomographic) option, which is capable of taking cross-sectional radiographic images. These images provide dimensional information for dental implant planning and information about location of impacted teeth.

7. Substantial equivalence chart

Name	Proposed device PAPAYA Plus	Predicate device PAPAYA Plus	Volumetric Tomography	Orthopantomograph® OP200, OP200D, Orthoceph®OC200, OC200D
Manufacturer	GENORAY Co., Ltd.	GENORAY Co., Ltd.	Instrumentarium Dental	Instrumentarium Dental
510(k) No.	K141700	K130419	K063773	K046312
Figure			*The Volumetric Tomography imaging option is used for Orthopantomograph® OP100 and OP200 product families.	
Indications for use	PAPAYA Plus is a digital extraoral source X-ray system intended to produce panoramic and cephalometric(option) images of the oral and craniofacial anatomy for a precise treatment planning in adult and pediatric care. The system is used for dental & skull radiographic examination and diagnosis of teeth, jaw, oral structure, and skull by exposing an X-ray image receptor to ionizing radiation, with a digital imaging capability for taking both panoramic and cephalometric images. And This system can be equipped Cust(Tomographic) option, which is capable of taking cross-sectional	PAPAYA Plus is a digital extraoral source X-ray system intended to produce panoramic and cephalometric(option) images of the oral and craniofacial anatomy for a precise treatment planning in adult and pediatric care. The system is used for dental & skull radiographic examination and diagnosis of teeth, jaw, oral structure, and skull by exposing an X-ray image receptor to ionizing radiation, with a digital imaging capability for taking both panoramic and cephalometric images.	Volumetric Tomography is intended to be used for producing cross-sectional (tomographic) radiographic images from the edentulous or dentate area of the jaws. The cross-sectional images provide dimensional information for dental implant planning and information about location of impacted teeth.	Orthopantomograph® OP200 (film unit) and OP200 D (digital unit) devices are intended to be used for producing X-ray radiographs of dentition, TM-joints and other oral structures. The units are capable of taking panoramic, TM-joint and maxillary sinus radiographs from patients. When the units are equipped with cephalometric option Orthoceph® OC200 (film unit) or OC200 D (digital unit) units can be used for cephalometric radiography and examinations related thereto. OP200 or OC200 units can also be equippmed with Ortho Trans (OT) option, which is capable of taking both

	radiographic images. These images provide dimensional information for dental implant planning and information about location of impacted teeth.			cross and longitudinal slices of region of interest. Ortho Trans uses linear tomography imaging principle.
Performance Specification	Panoramic and cephalometric	Panoramic and cephalometric	-	Panoramic and cephalometric
Input Voltage	120 V~	120 V~	-	110 V~, 50/60 Hz, 1.65kVA
Tube Voltage	60-90 kV	60-90 kV	-	57 - 85 kV
Tube Current	4-12 mA	4-12 mA	-	2-16 mA
Focal Spot Size	0.5 mm	0.5 mm	-	0.5 mm
Exposure Time	Standard panorama: 12 sec Cephalo (Normal): 8 sec	Standard panorama: 12 sec Cephalo (Normal): 8 sec	-	Panorama: 2.7-16 sec Cephalo: 0.2-19 sec
Exposure mode	Panorama: Panoramic mode TMJ mode SINUS mode CUST mode Cephalo: Cephalo mode	Panorama: Panoramic mode TMJ mode SINUS mode Cephalo: Cephalo mode	Volumetric Tomography	Panorama: Panoramic mode TMJ mode SINUS mode Linear Tomography Volumetric Tomography Cephalo: Cephalo mode
Image Receptor	Panoramic & cephalometric sensor : CdTe Sensor	Panoramic & cephalometric sensor : CdTe Sensor	-	Panoramic, Cephalometric sensor: CCD Detector

The proposed PAPAYA Plus has the same specification for mechanism as predicate device, PAPAYA Plus (k130419). The primary difference is to add the CUST mode in exposure modes which shows the cross-sectional images through reconstruction. CUST mode is similar with Volumetric Tomography (k063773) which reconstructs tomographic images.
The image performances and dosimetry of CUST mode have evaluated through clinical evaluation report. Evaluation results of dosimetry and images for safe and effective use of PAPAYA Plus are satisfied. We also had a licensed dentist review of panoramic, cephalometric and CUST images. She found them to have enough quality for diagnosis.

Therefore, PAPAYA Plus is deemed to be substantially equivalent to the predicate devices in safety and effectiveness.

8. Safety, EMC and Performance data comparison to Predicate

Device Safety, EMC and Performance data is same to predicate device which has been established in 510(k) submission K130419 as below. All test results were satisfactory.

- Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1, IEC 60601-1-1, IEC 60601-1-3, IEC 60601-2-7, IEC 60601-2-28 and IEC 60601-2-32, and IEC 61223-3-4 were performed.

- EMC testing was conducted in accordance with standard IEC 60601-1-2.

- FDA Guidance "Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Devices" was performed. The tests include the MTF, DQE and the dynamic range of the panoramic sensor and the cephalometric sensor. Both the MTF of the two detectors shows the resolution more than 80% at 2lp / mm and the DQE of them shows the performance of about 80% at 0lp / mm. The dynamic range of them shows more than 72dB.

- PAPAYA Plus meets the EPRC standards (21 CFR 1020.30. 31)

- PAPAYA Plus also meets the provisions of NEMA PS 3.1-3.18. Digital Imaging and Communications in Medicine (DICOM) Set.

- PAPAYA Plus was tested for safety and effectiveness related of the CUST in Clinical Evaluation report.

9. Conclusion

In reference to the comparison information provided in substantial equivalence chart, most of functions and electronic features are similar with predicate devices. The addition of CUST option was evaluated through the performance data. Thus PAPAYA Plus is substantially equivalent as compared with the predicate devices.